DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 3, 2015

U & I Corporation
Mr. Young-Geun Kim
Regulatory Affairs Specialist
20, Sandan-ro 76beon-gil (Road)
Uijeongbu-si, Gyeonggi-do
Republic of Korea 480-859

Re: K150570
Trade/Device Name: ANAX™ OCT Spinal System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: March 2, 2015
Received: March 6, 2015

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150570

Device Name
ANAX™ OCT Spinal System

Indications for Use *(Describe)*
ANAX™ OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. ANAX™ OCT Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, ANAX™ OCT Spinal System may be connected to Perfix™ Spinal System and ANAX™ 5.5 Spinal System rods with the rod connectors. Transition rods with differing diameters may also be used to connect ANAX™ OCT Spinal System to Perfix™ Spinal System and ANAX™ 5.5 Spinal System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

6. 510(k) Summary

Manufacturer:	U & I Corporation 20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 480-859
Sponsor:	U & I Corporation 20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 480-859
Sponsor Contact:	Young-Geun Kim, Regulatory Affairs Specialist +82 31 852 0102 (ext.619) ygkim@youic.com
Date Prepared:	June 02, 2015
Device Name:	ANAX™ OCT Spinal System
Classification Name:	Unclassified
Common Name:	Occipito-cervico-thoracic spinal fixation system
Product Code:	NKG, KWP
Primary Predicate Device:	VERTEX ® Reconstruction System (K143471)
Reference Devices:	VERTEX SELECT® Reconstruction System (K123656, K110522) Synapse System (K133698)

Description of Device:
ANAX™ OCT Spinal System is manufactured by U&I corporation. ANAX™ OCT Spinal System is for fixation the Cervicocranium (Occiput/C2), the true subaxial region (C3/C6), and the cervicothoracic junction (C7 to T2) by one system. The ANAX™ OCT Spinal System consists of polyaxial screws, polyaxial shank screws, hooks, rods, set screws, transverse(cross) links and occipital plate. Connectors are also provided for surgical convenience. ANAX™OCT Spinal System allows surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The single-use ANAX™ OCT Spinal System components are supplied as non- sterile and are

fabricated from medical grade titanium alloy (ASTM F136). All polyaxial screws have self-tapping function in the ANAX™ OCT Spinal System. Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the ANAX™ OCT Spinal System implants.

Indications for Use:

ANAX™OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine(C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g.pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. ANAX™OCT Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, ANAX™OCT Spinal System may be connected to Perfix™ Spinal System and ANAX™5.5 Spinal System rods with the rod connectors. Transition rods with differing diameters may also be used to connect ANAX™OCT Spinal System to Perfix™ Spinal System and ANAX™ 5.5 Spinal System.

Substantial Equivalence:

ANAX™ OCT Spinal System is substantially equivalent to VERTEX® Reconstruction System (K143471) in design, material, mechanical performance, function and intended use.

Comparison Technological Characteristics

The predicate and proposed device has the similar intended use, basic fundamental scientific technology, and the following similarities;

- The similar indications for use
- Similar design features
- Incorporate the same or similar materials
- The equivalent mechanical performance

Summary of Performance Data:

The mechanical performance of ANAX™ OCT Spinal System met the acceptance criteria which have been established from the predicate device.

Performance Testing

ANAX™ OCT Spinal System was tested in a non-clinical setting (bench testing) to assess that no new safety and efficiency issues were raised with this device. All tests met all acceptance criteria and that verifies performance of the ANAX™ OCT Spinal System is substantially equivalent to predicate devices.

The following tests were performed:

1) Worst case constructs of the occipito-cervical portion of ANAX™ OCT Spinal System were tested per ASTM F2706.
   - Static compression bending test
   - Static torsion test
   - Axial compression fatigue test
   - Axial torsion fatigue test

2) Worst case constructs of the thoracic portion of the ANAX™ OCT Spinal System were tested per ASTM F1717.
   - Static compression bending test
   - Static torsion test
   - Axial compression fatigue test
   - Axial torsion fatigue test

3) Worst case of subassembly of the ANAX™ OCT Spinal System were tested per ASTM F1798.
   - Axial gripping capacity test
   - Axial torque gripping capacity test

Conclusion:

The mechanical testing and published literature support the conclusion that the ANAX™ OCT Spinal System is substantially equivalent to predicate device with respect to indications for use and technological characteristics.